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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,757	11/20/2001	Linda M. Western	BEH-7270 Cont.	9649

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DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT PAPER NUMBER

1637

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/989,757

Applicant(s)

WESTERN ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35 and 37-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35 and 37-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/2/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. This action is in response to Applicants response, filed on May 28, 2004. Currently, claims 35 and 37-41 are pending. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. This action is made FINAL. Any objections and rejections not reiterated below are hereby withdrawn.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 35 and 37-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Gelfand et al (US Patent No. 5,210,015, cited in the IDS).

The claims are drawn to a composition comprising two oligonucleotides, the “first oligonucleotide” capable of reversibly hybridizing to a polynucleotide analyte under isothermal conditions to at least a portion” of a target polynucleotide, and a “second oligonucleotide capable of hybridizing to the polynucleotide analyte, wherein the “first oligonucleotide” comprises a 3’ portion that is substantially complementary to said polynucleotide analyte, and a 5’ portion which does not hybridize to the polynucleotide analyte, wherein the “second oligonucleotide”

hybridizes to said polynucleotide analyte at a location in the 3' direction from the "first oligonucleotide," the second oligonucleotide being substantially fully hybridized to the polynucleotide analyte at the temperature where the first oligonucleotide reversibly hybridizes with the polynucleotide analyte.

Gelfand teaches a method for detection of a target nucleic acid utilizing a 5'-nuclease and two oligonucleotides, a "labeled oligonucleotide" and a "first oligonucleotide," that contain sequences that are complementary to different regions of the same target (see, for example, col 2, lines 23-47; claim 1). Gelfand teaches that target and oligonucleotides are incubated together "under hybridization conditions, conditions which enable the binding of the primers and probes to the single nucleic acid strands" (col 8, lines 4-7). In reference to any oligonucleotide and target sequence, the term "hybridization conditions" inherently indicates reversible hybridization under isothermal conditions. It is an inherent property of any oligonucleotide with an unblocked 5' end that it would reversibly hybridize under isothermal conditions and, further, that it could be degraded at its 5' end by a 5' nuclease. Gelfand teaches that his "labeled oligonucleotide," like the "first oligonucleotide" of the instant claims, is cleaved by a 5'-nuclease; this cleavage causes the release of fragments that may comprise mononucleotides or small oligonucleotides (col 2, lines 23-47; claim 1; col 7, lines 11-15). Thus, Gelfand's "labeled oligonucleotide" may be "degraded" to provide a "first fragment that is substantially non-hybridizable" to a target and a "second fragment that is 3' of said first fragment" and "substantially hybridizable to said polynucleotide," as recited in the instant claims. Gelfand's "first oligonucleotide", like the "second oligonucleotide" of the instant claims, anneals to the target "such that the 3' end of the first oligonucleotide is adjacent to the 5' end of the labeled oligonucleotide" (col 2, lines 35-39); Gelfand discloses that "adjacent" oligonucleotides may abut one another, or be separated by "1 to about 20 nucleotides" (col 5, lines 61-67). Gelfand also teaches that two oligonucleotides can be labeled, either on their 5' or 3' ends (col. 10, ln. 51-68).

4. Claims 35 and 37-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Carrino et al. (USPN 5,573,907, cited in the IDS).

Carrino teaches a composition comprising two oligonucleotides, the “first oligonucleotide” capable of reversibly hybridizing to a polynucleotide analyte under isothermal conditions to at least a portion” of a target polynucleotide, and a “second oligonucleotide capable of hybridizing to the polynucleotide analyte, wherein the “first oligonucleotide” comprises a 3’ portion that is substantially complementary to said polynucleotide analyte, and a 5’ portion which does not hybridize to the polynucleotide analyte, wherein the “second oligonucleotide” hybridizes to said polynucleotide analyte at a location in the 3’ direction from the “first oligonucleotide” (see col. 2-4, 7-8, 12-14, 18-19 and 41-42, for example). Carrino also teaches the either one or both of the probes can be labeled either in the 5’ or 3’ end (col. 18-19); and 5’ portion of the first oligonucleotide can comprise about 1 to 40 nucleotides (col. 7, 9-10 and 41-42) (teaching that the 5’ portion of the first oligonucleotide can be any size).

5. Claims 35 and 37-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Urdea et al. (USPN 5,635,352).

Urdea teaches a composition comprising two oligonucleotides, the “first oligonucleotide” capable of reversibly hybridizing to a polynucleotide analyte under isothermal conditions to at least a portion” of a target polynucleotide, and a “second oligonucleotide capable of hybridizing to the polynucleotide analyte, wherein the “first oligonucleotide” comprises a 3’ portion that is substantially complementary to said polynucleotide analyte, and a 5’ portion which does not hybridize to the polynucleotide analyte, wherein the “second oligonucleotide” hybridizes to said polynucleotide analyte at a location in the 3’ direction from the “first oligonucleotide” (see Figs. 1-4, 7, 12-13, and cols. 2-3, 5-6, 10-13, for example). Urdea also teaches the either one or both

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of the probes can be labeled either in the 5' or 3' end (col. 16 and Figs. 1-4, 7, 12-13); and 5' portion of the first oligonucleotide can comprise about 1 to 40 nucleotides (Figs. 1-4, 7, 12-13, col. 6-12 and Examples 1-5) (teaching that the 5' portion of the first oligonucleotide can be any size).

Applicants Arguments

Applicants have amended Claim 35 to incorporate the limitations of Claim 36, wherein “the second oligonucleotide being substantially fully hybridized to the polynucleotide analyte at the temperature where the first oligonucleotide reversibly hybridizes with the polynucleotide analyte.” Applicants argue the references do not teach amended Claim 35.

Response to Applicants Arguments

Applicants' arguments have been considered, but are persuasive because the recitation of the second oligonucleotide being substantially fully hybridized to the polynucleotide analyte “at the temperature where the first oligonucleotide reversibly hybridizes with the polynucleotide analyte,” does not result in any structural difference between the claimed invention and the composition taught by the prior art of Gelfand, Carrino and Urdea. The “second oligonucleotide” taught by Gelfand, Carrino and Urdea would necessarily be “substantially fully hybridized to the polynucleotide analyte at the temperature where the first oligonucleotide reversibly hybridizes with the polynucleotide analyte,” since the “second oligonucleotide” of Gelfand, Carrino and Urdea meet the structural limitations of the “second oligonucleotide” of the claimed composition. Accordingly, because Claim 35 has been amended to recite only an inherent property of the composition of taught by Gelfand, Carrino and Urdea, the rejections are maintained.

6. No Claims are allowable.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

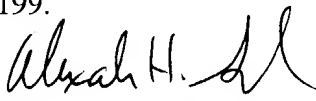
If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

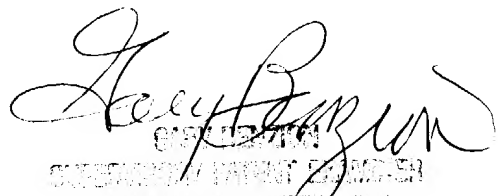
Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Alexander H. Spiegler
August 12, 2004


GARY BENZION
SUPERVISOR / PATENT EXAMINER
TECHNOLOGY CENTER 1600